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International Prosecution Strategy after *Therasense*: What You Need to Know Now

Shawn Gorman and Christopher Swickhamer, Banner & Witcoff, Ltd.

I. Introduction - The Plague of Inequitable Conduct Allegations

Intellectual property is of crucial importance to most sectors in the modern economy. Last year alone, the U.S. Patent & Trademark Office (PTO) received over a half million patent applications. Even more telling is the fact that this figure has doubled in just over a decade.[1] Obtaining rights, however, is only one side of the coin. As patents became increasingly important, attempts to invalidate those rights become more serious. One method that has garnered acceptance is claiming that a competitor's patent was granted though "inequitable conduct."

As previously reported by Bloomberg[2] the highly-anticipated federal court decision in *Therasense* set out to change the way "inequitable conduct" allegations were asserted.[3] The decision came from the Court of Appeals for the Federal Circuit, which handles patent cases and is second only to the Supreme Court for patent jurisprudence. Using harsh tones, the Federal Circuit criticized the "habit of charging inequitable conduct in almost every major patent case" as an "absolute plague," and noted how the existing doctrine is straining the court system, patent practitioners, and the PTO.[4] The *Therasense* decision dramatically reshaped and raised the standard for proving the inequitable conduct doctrine in patent cases. In light of the *Therasense* decision, this article discusses the disclosure requirements for submitting potentially relevant information to the PTO, including information obtained during prosecution of a foreign counterpart application, during the examination of a U.S. patent application.

II. The Roots of the Plague

Prior to the *Therasense* decision, courts applied a three factor test to prove inequitable conduct: (1) intent to deceive; (2) materiality; and (3) weighing the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable.[5] Complicating this test is that intent was balanced against materiality, to which *Therasense* referred as a "sliding scale."[6] For instance, if a reference was found to be highly material, then a lesser showing of intent to deceive was required.[7] Even simple negligence to cite a material reference had been found sufficient to meet the intent requirement.[8] This low standard has caused concern throughout the patent system. *Therasense* noted that patent examiners, patent practitioners, and the courts were all being strained.[9] Patent practitioners, fearful of failing to cite any reference that might be found material in litigation, cited nearly every document they came across to the PTO.[10] As a result, patent examiners were deluged with volumes of marginally material

prior art they are required to consider.[11] This burden appears to have been lifted.

III. Lifting the Burden

As justification for redirecting "a doctrine that has been overused to the detriment of the public,"[12] the Federal Circuit revisited the three Supreme Court cases providing the origins for the inequitable conduct doctrine. These cases dealt with "egregious misconduct," including:

> (1) filing a patent application even though the applicant knew of a possible prior use and filing an affidavit attempting to cover up the prior use;
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> (2) a patent attorney drafting an article describing an invention as a remarkable advance, having a well-known expert sign the article as his own, and then submitting the article to persuade the PTO to issue a patent; and
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> (3) active suppression of perjury before the PTO.[13]

Clearly, these examples warrant punishment. The Federal Circuit, however, noted that inequitable conduct was being stretched well beyond these cases, and made a decision to refocus the law.

Therasense revamped inequitable conduct law to now require proof, by clear and convincing evidence, of both intent to deceive, as the single most reasonable inference able to be drawn from the evidence, and "but-for" materiality.[14] Gone is the sliding scale, and intent may not be inferred from materiality.[15] The Federal Circuit further limited specific intent, indicating that "[p]roving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive."[16] For nondisclosure of information, the *Therasense* court noted that "clear and convincing evidence must show that the applicant *made a deliberate decisio*n to withhold a *known* material reference."[17] As to materiality, the Federal Circuit now requires "but-for" materiality.[18] For nondisclosure, such prior art is "but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art."[19] To muddy the situation somewhat, the *Therasense* court did provide an exception for materiality, noting that "affirmative acts of egregious misconduct" are material.[20]

Ultimately, *Therasense* attempts to refocus patent litigation on two foundational tenants: infringement and validity over the prior art. Oversights and mere negligence relating to citing of material prior art, by themselves, cannot be trumped up to prove inequitable conduct. Specific intent to deceive the PTO must be shown.

IV. Where Do We Go from Here?

Against this legal backdrop, the question remains how do inventors, patent attorneys, and in-house counsel (collectively referred hereafter as "patent applicants") comply with the duty of disclosure when prosecuting a family of related patent applications internationally.

Patent applicants should implement reasonable procedures to ensure that relevant prior art is being provided to U.S. examiners. Regardless of the *Therasense* decision, the PTO imposes a duty on patent applicants to provide material information to the PTO.[21] The PTO procedures list potential sources of material information, including: co-workers, trade shows, communications from or with competitors, potential infringers, or other third parties, related foreign applications, prior or co-pending United States patent applications, related litigation, and preliminary examination searches."[22] While *Therasense* has narrowed what constitutes inequitable conduct, patent applicants must still comply with PTO procedures.

Reasonable procedures obviously exclude any attempts to obtain a patent by fraud. False evidence, suppression of evidence, and the like are certainly not permitted. If a patent applicant is on the fence about whether to submit information or not, then the patent applicant should submit the information for consideration by the examiner. Nothing beneficial comes from withholding information that potentially could be material. In fact, you want the Examiner to consider a potentially relevant reference during the examination process when you, and not your competitors, are permitted to provide logical arguments explaining any distinguishing features. To further illustrate what courts may find to be reasonable procedures, we consider three scenarios that may come up when prosecuting foreign counterpart applications.

— A. Citing Corresponding Foreign Art

Patent applicants should still continue to cite prior art references to the PTO cited in foreign counterpart applications. For instance, if an applicant files a patent application in Europe claiming priority to a U.S. application, and a European examiner cites a reference not previously cited in the U.S., then that reference should be disclosed to the PTO. Even though *Therasense* modified the inequitable conduct standard, patent practitioners must still comply with the PTO guidelines.[23] Practically speaking, a patent attorney can review the identified prior art, but doing so is timely and expensive. Nor does attorney review mean that material disclosure might not be overlooked. It is better to avoid inequitable conduct issues altogether by submitting the prior art cited in a counterpart application for review by the U.S. examiner.

Continuing this scenario, is a patent applicant subject to inequitable conduct if a reference cited in a foreign office action is inadvertently not cited in the counterpart U.S. application, but turns out to be highly material to a patented claim? Assuming that all parties were not aware of the materiality, then, according to the *Therasense* decision, the answer would be no. Arguably, if a patent applicant is not aware of whether a reference is material or not, then they cannot have the requisite intent for inequitable conduct. Negligence, as noted by the *Therasense* court, is insufficient to show intent to deceive.[24]

Of course, if a client asks their attorney not to submit a reference to the PTO that was cited in a related foreign application, that could be a different story. At a minimum, the attorney should inquire for the reason the client does not want to submit the reference, and make an independent assessment about materiality. If the reference is material, the attorney should attempt to convince the client to submit the reference. If the client still does not agree to submit the reference to the PTO, the attorney, depending on the circumstances, may be required to disclose the prior art against their client's wishes to prevent perpetrating a fraud on the PTO and to withdraw.[25]

— B. Citing Foreign Office Actions

Under *Therasense*, a patent applicant is not required to blindly cite an office action issued by a foreign patent office to the PTO for fear of being accused of inequitable conduct. Providing only the prior art should be enough. While citing the foreign office actions is the safest course, it is not required. A possible reason for submitting it may be when:

> (1) the foreign office action has provided a different interpretation of a prior art reference than a U.S. examiner that is reasonable and arguably discloses a point of novelty argued in the U.S.;
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> (2) the U.S. examiner appears to have overlooked this interpretation; and

(3) the prosecuting attorney appreciated that this interpretation is both reasonable and was overlooked by the U.S. examiner.

Even if a patent applicant does not submit a foreign office action, a court would not necessarily find inequitable conduct under *Therasense* absent a showing of intent to deceive. The Federal Circuit has significantly reigned in the inequitable conduct doctrine, and suggests that only instances where the patent applicant intentionally deceived the PTO are improper. Nonetheless, having relevant art and arguments heard during the examination stage when only your client can rebut them is a much better position to be in than having your competitor craft their arguments and fight the validity of your patent – either through the PTO or through litigation proceedings.

— C. Citing Foreign Responses

In *Therasense*, the patentee may have taken inconsistent positions before the European Patent Office (EPO) relative to the PTO, but did not disclose this inconsistency to the U.S. examiner.[26] This issue must still be decided by a court looking at the specific facts before them.

As a general rule, a patent applicant is not required to submit responses filed in foreign related applications. A seemingly inconsistent position, in and of itself, is not sufficient to find inequitable conduct. The PTO, however, indicates that information is material if it "it refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability."[27]

Considering this, whether inequitable conduct is found in the *Therasense* litigation will likely turn on intent. If "but for" materiality is satisfied, then the patent examiner would not have allowed the claim at issue in *Therasense* but for lack of knowledge of the inconsistency. Even so, if the patent applicant was not aware of the inconsistency, or reasonably did not believe that the statements were inconsistent, there is no inequitable conduct because the patent applicant lacks the necessary deceptive intent. The *Therasense* decision now requires actual knowledge, whereas a "finding that the misrepresentation or omission amounts to gross negligence . . . under a 'should have known' standard does not satisfy this intent requirement."[28]

Looking to the facts set forth in the *Therasense* decision, there appears to be a question whether the statements made to the EPO and the PTO were actually inconsistent, as the Federal Circuit sent the case back to the district court to be reconsidered under the revised inequitable conduct standard.[29] If reasonable people could disagree about whether the statements made to the PTO and EPO are inconsistent, the district court may very well be reluctant to find inequitable conduct.

One method of minimizing chances of inconsistencies is to utilize the same attorney prosecuting a U.S. application to provide instructions and arguments to foreign colleagues during the substantive examination of foreign counterparts. Using different attorneys could create a potential that positions taken abroad are inconsistent with positions taken in the U.S.

Even if there is an inconsistency, proving that the inconsistency is intentional under *Therasense* may be difficult. Of course, direct evidence that the applicant knew of the materiality of the inconsistency would likely be sufficient to show intent to deceive. Such evidence would likely be in the form of written communication, such as an email or letter, showing knowledge of the inconsistency. While not impossible, it would likely be difficult to explain why the U.S. examiner was not informed of the inconsistency.

Therasense does provide some guidance on the type of evidence necessary to prove specific intent to deceive, absent direct evidence of intent. The

Federal Circuit stated that a court may "infer intent from indirect and circumstantial evidence."[30] However, the Federal Circuit limited what inferences may be made. The Court noted that "to meet the clear and convincing evidence standard, the specific intent to deceive must be the 'single most reasonable inference able to be drawn from the evidence.'"[31] Intent to deceive cannot be found when multiple reasonable inferences can be drawn, and even lacking a good faith explanation for withholding a material reference is insufficient.[32] While infringers will undoubtedly look for loopholes in the Court's reasoning, the Federal Circuit has provided many obstacles to proving inequitable conduct without direct evidence showing intent to deceive.

V. Conclusion

In sum, patent applicants need to take reasonable steps to keep the PTO apprised of prior art cited in counterpart foreign applications. Citing the prior art references identified by foreign examiners is one important step to avoiding claims of inequitable conduct. Another is having the same attorney who is prosecuting the U.S. application also work with foreign associates during prosecution of counterpart applications. This minimizes the chances that inconsistent positions will be taken in the U.S. and abroad, and the attorney can aid in determining when a position is material such that the U.S. examiner should be informed. *Therasense* has thus attempted to narrow the doctrine of inequitable conduct, and will likely serve to focus patent litigation on issues of validity over the prior art and infringement.

Shawn P. Gorman is a shareholder and Christopher M. Swickhamer is an associate in Banner & Witcoff's Chicago office. Mr. Gorman's practice focuses on patent prosecution and counseling in a wide variety of technology areas. Mr. Swickhamer concentrates his practice on patent litigation, prosecution and counseling in electrical and computer technologies. Mr. Gorman and Mr. Swickhamer can be reached at sgorman@bannerwitcoff.com and cswickhamer@bannerwitcoff.com. *This article is for educational and informational purposes only and should not be construed in any way as legal advice. The article reflects the opinion of the authors and should not be attributed to the firm Banner & Witcoff or to any of its clients*

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1 http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm
2 http://www.bloomberg.com/news/2011-05-25/abbott-wins-ruling-to-narrow-patent-misconduct-standard.html
3 *Therasense, Inc. v. Becton, Dickinson and Company*, 2011 BL 137835 (Fed. Cir. May 25, 2011) (*en banc*).
4 *Id.* at p. 23.
5 *Id.* at p. 19.
6 *Id*. at p. 20.
7 *Id*.
8 *Id*.
9 *Id*. at p. 23.
10 *Id*.
11 *Id*.
12 *Id*. at p. 24.
13 *Id*. at p. 15, *citing Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).
14 *Id.* at p. 25.
15 *Id*.
16 *Id*.
17 *Id*. at p. 24 (emphasis in original).
18 *Id*. at p. 27.
19 *Id*.
20 *Id*. at p. 29.
21 *See* 37 C.F.R. 1.56.
22 *See* Manual of Patent Examination Procedure (MPEP) § 2001.06.
23 *Id.*
24 *Therasense* at p. 24.
25 *See* 37 C.F.R. 10.40 and 10.85.
26 *Therasense* at pp. 10-13.
27 *See* 37 C.F.R. 1.56(b).

28 *Therasense* at p. 24.
29 *Id*. at pp. 36-37 ("On remand, the district court should determine whether there is clear and convincing evidence that Sanghera or Pope knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO").
30 *Id*. at p. 25.
31 *Id*. at p. 25, citing *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009).
32 *Id*. at pp. 25-26.